

REMARKS

Claims 1, 3, 4, 6-17, and 21-24 are pending in the application, with Claims 11-17 and 21-24 under examination and Claims 1, 3, 4, 6-10, and 18-20 withdrawn. With the entry of this Response, Claims 1, 6, 9, 11, 14-16, and 22 are amended, Claims 18-20 are canceled, and Claims 25-27 are new. The amendments to the claims are supported by the application as originally filed and do not introduce new matter. For reference purposes, all citations to the pending Application refer to U.S. Patent Application Publication No. 2004/0096410.

OBJECTION TO CLAIMS 14 AND 16

The Examiner objects to Claims 14 and 16 because “they lack a subject between ‘The’ and ‘of Claim 11.’ ” Applicants respectfully submit that this objection is overcome in view of the present amendments. Therefore, Applicants respectfully request the Examiner to withdraw this objection.

REJECTION OF CLAIMS 11-17 AND 22-24 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The Examiner rejected Claims 11-17 and 22-24 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. The Examiner stated that “support for the [the limitation ‘hydrophilic polymer network’] is lacking and the addition of said limitation is new matter.” Applicants respectfully traverse this rejection.

Applicants submit that there is sufficient written description for the phrase “hydrophilic polymer network” to inform a skilled artisan that Applicants were in possession of the claimed invention as a whole at the time the application was filed. According to MPEP § 2163 “what is conventional or well known to one of ordinary skill in the art need not be disclosed in detail.”¹ Furthermore, “[i]f a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met.”² The claims need not be in *ipsis verbis* (i.e., “in the same words”) to be sufficient. Applicants respectfully

¹ See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384. See also *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005).

² See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972)

submit that a skilled artisan would have understood the inventor to be in possession of the claimed “hydrophilic polymer network.”

Nonetheless, in order to facilitate prosecution of the present invention, Applicants amend the claims to recite a “hydrophilic polymer matrix.” Support for this amendment can be found in Applicants’ Specification in at least ¶¶ 24, 51, 56, 59, 61, 69, and 79-83. Thus, Applicants respectfully request the Examiner to withdraw this rejection.

REJECTION OF CLAIMS 11-17 UNDER 35 U.S.C. § 102(b)

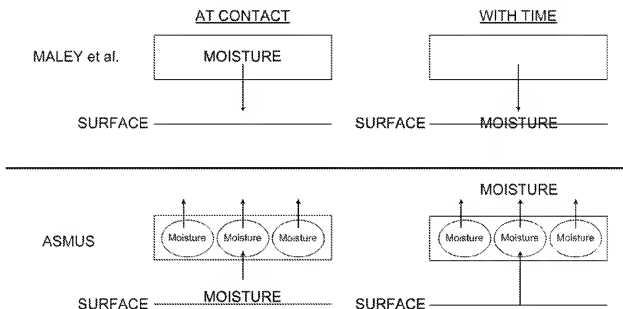
The Examiner rejected Claims 11-17 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent no. 5,270,358 to Asmus (hereinafter, “Asmus”). The Examiner stated that Asmus “discloses a transdermal composition comprising . . . a hydrogel of instant claim 11; the active agent of instant claim 11; the humectant (e.g. glycerol) of instant claim 11; the moisture content of instant claim 11; [and] the organic acid of instant claim 11” Applicants respectfully traverse this rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Applicants respectfully submit that Asmus does not set forth each and every element of the currently amended claims. Therefore, Asmus does not anticipate the presently claimed invention.

Asmus teaches a “gel-adhesive composite . . . compris[ing] a two phase system.” (Asmus, Col. 4, lines 46-47). Asmus teaches a “gel adhesive composite [that] requires at least three components: (1) a pressure sensitive adhesive as a continuous matrix; and in the dispersed gel, (2) a hydrocolloid and (3) a swelling agent for the hydrocolloid.” (Asmus, Col. 2, lines 42-45). In the composition of Asmus, the hydrocolloid “gel particles dispersed in the continuous adhesive matrix provide the means by which moisture at the skin is continuously removed by diffusion of moisture through the gel adhesive layer.” (Asmus, Col. 18, lines 18-22). The hydrocolloid gel particles with a swelling agent “continuously dry an otherwise wet environment by the transmission of moisture from the skin or the skin opening while the adhesive matrix maintains adhesion.” (Asmus, Col. 18, lines 42-45). Asmus teaches a moisture removal system.

The composition of Asmus does not anticipate the presently claimed invention because there is no teaching in Asmus of a composition that establishes a diffusion gradient wherein moisture is provided from the composition to a surface. Asmus teaches a hydrophobic adhesive

matrix having particles of a hydrocolloid gel dispersed within the matrix that have a high moisture vapor rate wherein moisture is moved from the contacted surface to the outer surrounding environment. (Asmus, Col. 16, lines 36-38; *see also* Figure 1). The composition of Asmus has a “high moisture vapor transmission rate . . . [that] facilitates removal of moisture or other fluid from the area where the composite is adhered.” (Asmus, Col. 3, lines 45-48). Asmus discloses a moisture removal composition, not a moisture delivering composition. (*See*, Figure below). Considering that Asmus only discloses a moisture removal composition, Asmus cannot teach a composition such as the currently claimed invention, which delivers moisture from the composition to the contacted ungual surface.



In addition, Asmus does not anticipate the presently claimed invention because there is no teaching in Asmus of a hydrophilic polymer matrix directly contacting an ungual structure. Asmus teaches a hydrophobic adhesive matrix having particles of a hydrocolloid gel dispersed within the matrix that have a high moisture vapor rate, wherein moisture is moved from the contacted surface to the outer surrounding environment. (Asmus, Col. 16, lines 36-38; *see also* Figure 1). Asmus teaches contacting a skin surface with a hydrophobic adhesive matrix that is “immiscible with water or other hydrophilic liquids.” (Asmus, Col. 3, lines 7-8). The hydrophobic adhesive matrix contacts the surface and adheres the Asmus composition to the skin

surface. Asmus teaches that a hydrophilic matrix lacks “general utility [for] skin adhesives.” (Asmus, Col.1, lines 36). In Asmus, the hydrocolloid particles are buried within the hydrophobic adhesive matrix because of their lack of adhesive properties and to create a high diffusion environment for moisture. Thus, Asmus cannot teach directly contacting a hydrophilic polymer matrix with an ungual structure.

Furthermore, Asmus does not anticipate the presently claimed invention because there is no teaching in Asmus of a continuous hydrophilic polymer matrix. Asmus teaches a two phase composition comprising a hydrophobic pressure sensitive adhesive as a continuous matrix having hydrocolloid particles dispersed within the hydrophobic matrix. The hydrocolloid component of the Asmus composition consists of ground hydrocolloid particles (See, Asmus, Example1) that are dispersed in a hydrophobic pressure sensitive adhesive (See, Asmus, Examples 2 and 4). Asmus teaches a 2 phase discontinuous matrix. Thus, Asmus cannot teach or disclose a continuous hydrophilic polymer matrix. Therefore, Asmus does not teach the presently claimed invention.

For at least the above reasons, Applicants respectfully submit that Asmus does not disclose each and every element of the currently claimed invention. Therefore, Asmus does not anticipate the presently claimed invention. Applicants respectfully request the Examiner to withdraw this rejection.

REJECTION OF CLAIMS 21-24 UNDER 35 U.S.C. § 103(a)

Claims 21-24 were rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,270,358 to Asmus (hereinafter, “Asmus”). The Examiner stated that “Asmus discloses a transdermal composition comprising a hydrogel [and] . . . provides utility for skin adhesive applications. While Asmus does not explicitly teach the percentages of instant claims 21-23, it is the position of the Examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation” Applicants traverse this rejection.

A claimed invention is patentable when the prior art fails to teach the claimed subject matter as a whole. 35 U.S.C. § 103(a); *see also* MPEP § 2141. Applicants respectfully submit that Asmus does not teach or suggest all of the claim features as a whole, for example, there is no

teaching in Asmus of a composition having a diffusion gradient wherein moisture moves from the composition to the contacted site. Asmus teaches a “gel adhesive composite [that] requires at least three components: (1) a pressure sensitive adhesive as a continuous matrix; and in the dispersed gel, (2) a hydrocolloid and (3) a swelling agent for the hydrocolloid.” (Asmus, Col. 2, lines 42-45). In the composition of Asmus, the hydrocolloid “gel particles dispersed in the continuous adhesive matrix provide the means by which moisture at the skin is continuously removed by diffusion of moisture through the gel adhesive layer.” (Asmus, Col 18, lines 18-22). The hydrocolloid gel particles with a swelling agent “continuously dry an otherwise wet environment by the transmission of moisture from the skin or the skin opening while the adhesive matrix maintains adhesion.” (Asmus, Col. 18, lines 42-45).

The composition of Asmus does not render the presently claimed invention obvious because Asmus teaches an adhesive matrix having particles of a hydrocolloid gel dispersed within the matrix that remove moisture from a surface. The composition of Asmus has a “high moisture vapor transmission rate . . . [that] facilitates removal of moisture or other fluid from the area where the composite is adhered.” (Asmus, Col. 3, lines 45-48). The composition of Asmus discloses a moisture removal composition, not a moisture delivering composition, as is illustrated in the Figure above. Considering that Asmus discloses a composition that functions as a moisture removal composition, Asmus cannot teach or suggest a composition that comprises a moisture delivery system.

Given the difference between the directionality of the diffusion gradients in Asmus and the presently claimed invention, a person having ordinary skill in the art would not have a reasonable expectation of success in adapting the teachings of Asmus to result in the presently claimed invention. The composition of Asmus removes moisture from the skin to the composition and beyond. The other components of the Asmus composition do not alter this fundamental aspect of moisture removal, and thus do not provide a teaching or suggestion of components of Applicants’ currently claimed invention.

The Examiner also stated that “[i]t would have been obvious to a person of ordinary skill in the art at the time of the invention was made to disclose a composition comprising a hydrogel, at least one active agent, at least one humectant as taught by Young, et al. . . because it is useful in cleansing the skin.” Applicants respectfully submit that the Examiners argument is unclear. This statement is the only reference to “Young et al.”, and this reference was not further

identified by the Examiner and a Notice of References Cited was not provided with the Final Office Action. Applicants respectfully request the Examiner to clarify this argument and identify the reference or to withdraw this rejection.

Applicants respectfully submit that Asmus does teach or suggest the presently claimed invention as a whole. Applicants also submit that there is no reasonable expectation of success in adapting the teachings of Asmus to result in the presently claimed invention. Applicants submit that Asmus does not teach or suggest the currently claimed invention. Therefore, Applicants respectfully request the Examiner to withdraw this rejection.

RESPONSE TO EXAMINER'S ARGUMENTS

The Examiner states that "the Asmus invention would deliver moisture if applied to a hydrophilic surface. . . Properties are the same with the structure and composition are the same." Applicants respectfully submit that the Examiner has made an improper assumption regarding the inherency of the Asmus reference.

According to MPEP § 2112, "the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic."³ The extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill."⁴ Mere probabilities or possibilities are insufficient. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."⁵

There is no reasoning in Asmus to reasonably support the assumption, stated in the Office Action, "that the Asmus invention would deliver moisture if applied to a hydrophilic surface" necessarily flows from the teachings of the applied prior art. In stark contrast to the Examiner's assumption, the invention of Asmus is expressly directed to a composition comprising hydrocolloid "gel particles dispersed in the continuous adhesive matrix [that] provide the means by which moisture at the skin is continuously removed by diffusion of moisture through the gel

³ *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993).

⁴ *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999).

⁵ *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

adhesive layer.” (Asmus, Col. 18, lines 18-22). Asmus only teaches the removal of moisture from the skin. Asmus neither teaches nor suggests the delivery of moisture to a surface. Therefore, Applicants respectfully submit that the Examiner’s unsubstantiated reasoning that the Asmus invention and the presently claimed invention are equivalent is both improper and incorrect.

Consequently, Applicants respectfully submit that the Examiner’s conclusion that “[p]roperties are the same when structure and composition are the same” is also incorrect. The invention of Asmus has entirely different properties, structures, and compositions than that of the presently claimed invention. Asmus teaches a two phase composition comprising a hydrophobic pressure sensitive adhesive as a continuous matrix having hydrocolloid particles dispersed within the hydrophobic matrix, wherein the hydrocolloid particles have a high moisture vapor rate, moving moisture from the contacted surface. Asmus does not disclose a composition that establishes a diffusion gradient wherein moisture is provided from the composition to a surface. Further, Asmus does not disclose a continuous hydrophilic polymer matrix. Therefore, Asmus neither teaches nor suggests the structure, composition, properties or function of the present invention.

The Examiner also stated that “there is no indication in the claim language that the dermal structure will be subject to increased moisture as a result of the diffusion gradient.” Applicants respectfully submit that Claim 11 recites that moisture is transferred by the diffusion gradient from the hydrophilic polymer matrix composition to the dermal structure. Therefore, Applicants are unclear as to the Examiner’s reading of the claims.

For at least these reasons, Applicants respectfully submit that Asmus does not teach or suggest the currently claimed invention. Therefore, Applicants respectfully request the Examiner to withdraw this rejection.

CONCLUSION

The foregoing is a complete response to the Action dated June 26, 2008. Applicants respectfully submit that the pending claims are patentable. Early and favorable consideration is solicited.

Applicants file this response solely to facilitate prosecution. As such, Applicants reserve the right to pursue claims of broader or similar scope as originally filed in a continuation

application or other application after allowance of the present application. Applicants do not concede that the current or past rejections are correct and reserve the right to challenge such rejections later in prosecution or on appeal. Accordingly, any amendment, argument, or claim cancellation is not to be construed as abandonment or disclaimer of subject matter. Because certain of the current amendments may include broadening amendments, Applicants respectfully request the Examiner to revisit any previously reviewed references cited in this Application to further ensure that the currently pending claims remain patentable over any previously reviewed references.

The Commissioner is hereby authorized to charge the fee of \$810 for the Request for Continued Examination, and the one month extension of time fee. Applicants do not find that any other fees are currently due, but the Commissioner is hereby authorized to charge any other fees that may be required, or to credit any overpayment, to Deposit Account No. 20-1507.

If the Examiner believes there are other issues that can be resolved by a telephone interview, or that there are any informalities that remain in the application which may be corrected by the Examiner's amendment, a telephone call to the undersigned attorney at (404) 885-3652 is respectfully solicited.

Respectfully submitted,

/MaryAnthonyMerchant Reg.No.39,771/

Mary Anthony Merchant, Ph.D.
Reg. No. 39,771

TROUTMAN SANDERS LLP
Bank of America Plaza
600 Peachtree Street, N.E.
Suite 5200
Atlanta, Georgia 30308-2216
Telephone: (404) 885-3652
Facsimile: (404) 962-6527
ACRY4.CIP